FORM PTO 1390 (REV. 12-29-99) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: KEIL/149/PC/US

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 10/019714

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP99/05696	August 6, 1999	August 6, 1999

TITLE OF INVENTION: Tracheal Cannula

APPLICANT(S) FOR DO/EO/US: Bernhard Eistert

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or Declaration of the Inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 16 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST Preliminary Amendment.
    A SECOND or SUBSEQUENT Preliminary Amendment.
14. ☒ A substitute specification.
15. ☐ A change of Power of Attorney and/or address letter.
16. ☒ Other items or information:

    Copy of IPER

EXPRESS MAIL mailing label number EV010451000US

I, Talisha L. Cooper, hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on December 28, 2001 and is addressed to "Box PCT, Commissioner for Patents, Washington, DC 20231."

Talisha L. Cooper

U.S. APPLICATION NO. (if known, see 37CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/019714	PCT/EP99/05696	KEIL/149/PC/US

17. ☒ The following fees are submitted:		CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):			
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37CFR 1.445 (a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	$		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$ 890.00		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	$		
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33 (1) – (4)	$		
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims satisfied provisions of PCT Article 33 (1) – (4)	$		
ENTER APPROPRIATE BASIC FEE AMOUNT =		$ 890.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		$	

CLAIMS	NUMER FILED	NUMBER EXTRA	RATE		
Total claims	20 - 20 =		X $	$	
Independent claims	3 - 3 =		X $	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $	$	
TOTAL OF ABOVE CALCULATIONS =				$ 890.00	
Reduction of ½ for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				$ 445.00	
SUBTOTAL =				$ 445.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)) +				$	
TOTAL NATIONAL FEE =				$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property. +				$	
TOTAL FEES ENCLOSED =				$ 445.00	
				Amount to be refunded:	$
				Charged:	$

a. ☒ A check in the amount of $ 445.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account Number 16-2563 in the amount of $_____ to cover the above fees. *A duplicate copy of this sheet is enclosed.*

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 16-2563 *A duplicate copy of this sheet is enclosed.*

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Guy D. Yale, Esq.

Alix, Yale & Ristas, LLP
750 Main Street, Suite 1400
Hartford, Connecticut 06103

SIGNATURE

Guy D. Yale

NAME

29,125

REGISTRATION NUMBER

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Bernhard Eistert

Serial No.: Examiner:

Filing Date: Group Art Unit:

International Serial No.: PCT/EP99/05696

International Filing Date: August 6, 1999

For: Tracheal Cannula

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 2327
Arlington, Virginia 22202

Sir:

PRELIMINARY AMENDMENT

Before calculating the filing fee and examining the application, please enter the following amendments:

The amendments are made with respect to the English translation of the German text of PCT/EP99/05696 as submitted herewith.

In the Specification:

Page 1, after line 5, insert —BACKGROUND OF THE INVENTION—

Page 3, after line 2, insert —SUMMARY OF THE INVENTION—

Page 4, after line 7, insert —BRIEF DESCRIPTION OF THE DRAWINGS—

Page 4, after line 12, insert —DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS—

Page 6, delete in entirety.

In the claims:

Please amend claims 1 to 6 as follows:

1. (amended) A tracheal cannula for insertion into the trachea [(9)] following a tracheotomy, having a shaft [(2)] and a cuff [(3)] for blocking the tracheal cross-sectional area surrounding the shaft [(2)], characterized such that in the section of the shaft [(2)] lying above the cuff [(3)] a window [(4)] is constructed, such that this is covered by an air-permeable membrane [(5)].

2. (amended) Tracheal cannula based on [Claim] claim 1, characterized such that the membrane [(5)] is not permeable to water.

3. (amended) Tracheal cannula based on [Claim] claim [1 or] 2, characterized such that the membrane [(5)] consists essentially of polytetrafluoroethylene (PTFE).

4. (amended) Tracheal cannula based on [Claim 3] claim 2, characterized such that the membrane [(5)] comprises [consists essentially of a fabric made of PTFE lacing] polytetrafluoroethylene (PTFE).

5. (amended) Tracheal cannula based on [one of the claims 1-4] claim 3, characterized such that the membrane comprises a fabric made of PTFE lacing [at the entrance (11) of the cannula (1) a valve is provided, which opens upon inhalation and closes upon exhalation].

6. (amended) Tracheal cannula based on [one of the claims 1 to 5] claim 4, characterized in [such] that the membrane consists of a fabric made of PTFE lacing [cuff (3) is connected via a line (7) to a pilot balloon (8) or the like for the inflation of the cuff (3) and for controlling the cuff pressure].

Please add new claims 7 through 20.

7. Tracheal cannula based on claim 1, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

8. Tracheal cannula based on claim 2, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

9. Tracheal cannula based on claim 3, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

10. Tracheal cannula based on claim 4, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

11. Tracheal cannula based on claim 5, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

12. Tracheal cannula based on claim 6, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

13. Tracheal cannula based on claim 1, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

14. Tracheal cannula based on claim 2, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

15. Tracheal cannula based on claim 3, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

16. Tracheal cannula based on claim 4, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

17. Tracheal cannula based on claim 5, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

18. Tracheal cannula based on claim 6, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

19. Tracheal cannula based on claim 7, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

20. Tracheal cannula based on claim 13, wherein said balloon means comprises a pilot balloon.

In the Abstract:

Please cancel the Abstract and enter the Abstract of the Disclosure on the separate sheet enclosed herewith.

A SUBSTITUTE SPECIFICATION INCORPORATING THE AMENDMENTS IS ENCLOSED HEREWITH.

REMARKS

Applicant has amended the English translation of the EP application to conform the specification to U.S. patent practice. Numeric identifiers have been canceled from the claims and multiple dependencies have been eliminated.

An Abstract of the Disclosure has been submitted on a separate sheet.

Upon entry of the amendments, claims 1 through 20 will be under consideration for the U.S. national phase.

Respectfully Submitted,

Bernhard Eistert

By: _____

Guy D. Yale
Registration No. 29,125
Alix, Yale & Ristas, LLP
Attorney for Applicant

Date: December 28, 2001
750 Main Street
Hartford, CT 06103-2721
(860) 527-9211
Our Ref: KEIL/149/PC/US

GDY/tlc

2/pats

Tracheal cannula

This invention relates to a tracheal cannula for insertion into the trachea following a tracheotomy, with this cannula having a shaft and a cuff for blocking the tracheal cross-sectional area surrounding the shaft.

Following a tracheotomy, a cannula is inserted into the trachea in order to keep open the lumen thereby created. Available to this end are cannulas in diverse forms and made of various materials. Thus, thin-walled silver cannulas are familiar that are constructed in a double-barreled form, namely they have an outer cannula and an inner cannula that is easy to remove. Furthermore there are also more thick-walled plastic cannulas that in contrast to metal cannulas are not as rigid and that at body temperature conform roughly to the shape of the surrounding space, without their lumen thereby changing.

When there is an increased risk of aspiration, a tracheal cannula with a so-called blocker cuff is used, which is intended to prevent any entering of saliva, gastric juice, or other fluids or food (aspiration). These cuffs are normally positioned around the shaft of the cannula or are integrated within it, and can be inflated in order to conform to the surrounding space of the trachea.

Finally there are artificial larynxes, which are equipped with a valve mechanism and a hole or a screen on their shaft in order to make it possible for the patient to vocalize. When the patient

inhales, the valve mechanism at the cannula entrance opens up and permits the intake of air through the cannula into the lungs. On the other hand, in exhalation the valve closes and the air stream is led out through the larynx in a normal way via the cannula hole or window, thus enabling both a normal air intake and also the use of the voice. However, such artificial larynxes can be used only in patients who are not at risk for aspiration, so that those who are at such a risk have no way to speak. Whereas this is still tolerable for patients in the transitional stage immediately after a tracheotomy, the inability to vocalize over a long period of time is quite difficult to accept, especially in the case of neurologically impaired patients with a protracted risk for aspiration (for example, following a stroke).

Familiar from US 4 459 984 is a tracheal cannula of this species for insertion into the trachea. This device comprises a curved cannula that has an inflatable cuff positioned around the end of the cannula that is within the trachea. Above the cuff, the tracheal cannula has an escape nozzle or opening that can be closed by a flap valve and that can be opened by increasing the air pressure in the tracheal cannula, so that air escapes into the upper esophagus and the patient can speak during the mechanical evacuation of air. However because of this valve, which is intended to prevent aspiration when in the closed state, the air stream is deflected and slowed down considerably. This causes the natural vocalization characteristics in the larynx to be impaired. Furthermore when the inner pressure in the tracheal cannula slackens, the valve is abruptly closed and thereby prevents vocalization from continuing. Moreover due to the possibility that the flap of the valve may jam, a risk of aspiration cannot be excluded with certainty.

Therefore one object of the invention is to make possible in a reliable way a vocalization that is as natural as possible in patients equipped with tracheal cannulas that have a cuff.

By means of the invention, this object is essentially achieved by constructing a window in the section of the shaft lying above the cuff, with this window being covered by a membrane that is permeable to air. This membrane thereby prevents the entry of saliva and food particles into the cannula and thus into the lower airways. But on the other hand, speaking is made possible because of the air permeability of the membrane.

In accordance with one preferred embodiment of the invention the membrane is not permeable to water, so as to ensure that no saliva or nutrient components enter into the cannula. It has turned out to be especially advantageous in this connection to use a membrane made of polytetrafluoroethylene (PTFE), especially a fabric made of PTFE such as can be obtained on the commercial market under the trade name of Gore-Tex®.

In the inhalation process the air is carried through the cannula into the lungs, whereas for speaking purposes the patient can hold closed the cannula in order for the air to go through the membrane into the larynx. However, in accordance with one preferred embodiment of the invention, a provision is made to have a valve situated at the entrance of the cannula, with this valve automatically opening with inhalation and closing with exhalation.

In one improvement of the invention, the cuff is connected via a line to a pilot balloon or the like for the inflation of the cuff and for controlling the cuff pressure.

Other aims, advantages, and possible applications of the invention appear from the following description of an exemplary embodiment and from the drawings. Here all the described and/or graphically represented features form the subject of the invention by themselves or in any given combination, regardless of how they are summarized in the claims or of any of their back-references.

These show:

Figure 1, a schematic view of the tracheal cannula in accordance with the invention, and

Figure 2, the tracheal cannula shown in schematic fashion when inserted into the trachea of a patient.

As can be seen from the drawings, a tracheal cannula 1 in accordance with the invention consists essentially of a hollow shaft 2, within whose lower section a cuff 3 is provided. This cuff 3 can be slipped onto the shaft 2 or can be constructed to form a one-piece unit with this. Above the cuff 3 a window 4 is constructed in the shaft 2, with this window being covered with an air-permeable but not water-permeable membrane 5. This membrane consists preferably of a fabric such as can be obtained on the commercial market under the trade name of Gore-Tex®. Provided at the front section of the shaft 2 are holding arms 6 by means of which the positioning and attachment of the tracheal cannula 1 on the throat of the patient can be accomplished. Via a line 7, which is connected with a pilot balloon 8, the cuff 3 can be inflated and the cuff pressure can be controlled. The line 7 can be designed to be removable from the cannula.

Following a tracheotomy the tracheal cannula 1 is shown as in Figure 2, with it being inserted into the trachea 9 of the patient. In this connection, it must be made sure that the membrane-protected window 4 of the shaft 2 lies within the tracheal lumen of the trachea 9, so that in an exhalation it is ensured that the air is carried into the larynx 10. After the insertion of the tracheal cannula 1, the cuff 3 is inflated with the aid of the pilot balloon 8 or in some other suitable way such that it conforms to the cross-sectional area of the trachea and thus closes the trachea. Thereby the lungs can be supplied with air only via the cannula 1.

In an inhalation, the air is sucked in through the intake 11 of the tracheal cannula 1 and is conveyed into the lungs. When exhaling, a valve, not shown, closes the cannula 1, so that the air stream escapes through the membrane-protected window 4 into the larynx 10 and the patient is rendered able to speak.

In a different, simpler embodiment, no valve is provided in the tracheal cannula 1, so that in order to speak the patient must hold shut the cannula 1 during the exhalation process.

In this way, by means of the invention any entry of fluid into the trachea is reliably prevented, whereas in exhaling the air goes through the membrane into the larynx, so that the patient is able to speak.

List of reference numbers:

1	Tracheal cannula
2	Shaft
3	Cuff
4	Window
5	Membrane
6	Holding arm
7	Line
8	Pilot balloon
9	Trachea
10	Larynx
11	Entrance

Patent Claims:

1. A tracheal cannula for insertion into the trachea (9) following a tracheotomy, having a shaft (2) and a cuff (3) for blocking the tracheal cross-sectional area surrounding the shaft (2), characterized such that in the section of the shaft (2) lying above the cuff (3) a window (4) is constructed, such that this is covered by an air-permeable membrane (5).

2. Tracheal cannula based on Claim 1, characterized such that the membrane (5) is not permeable to water.

3. Tracheal cannula based on Claim 1 or 2, characterized such that the membrane (5) consists essentially of polytetrafluoroethylene (PTFE).

4. Tracheal cannula based on Claim 3, characterized such that the membrane (5) consists of a fabric made of PTFE lacing.

5. Tracheal cannula based on one of the claims 1 to 4, characterized such that at the entrance (11) of the cannula (1) a valve is provided, which opens upon inhalation and closes upon exhalation.

6. Tracheal cannula based on one of the claims 1 to 5, characterized such that the cuff (3) is connected via a line (7) to a pilot balloon (8) or the like for the inflation of the cuff (3) and for controlling the cuff pressure.

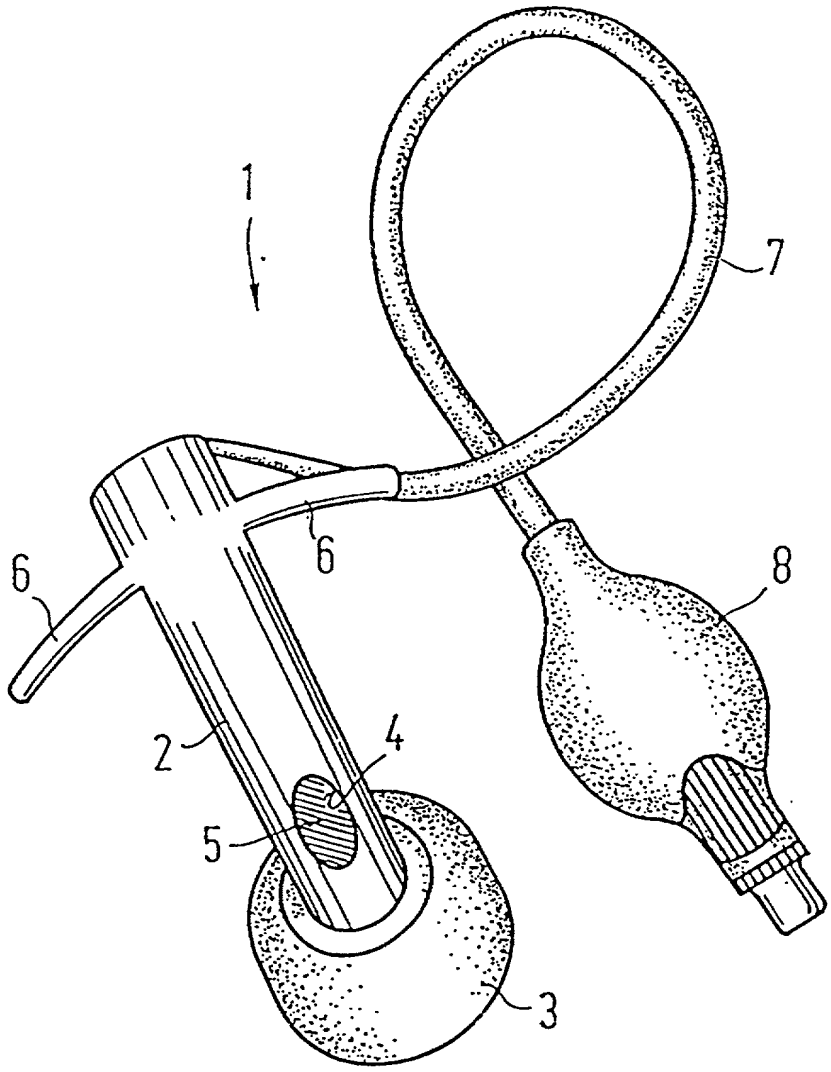

FIG. 1

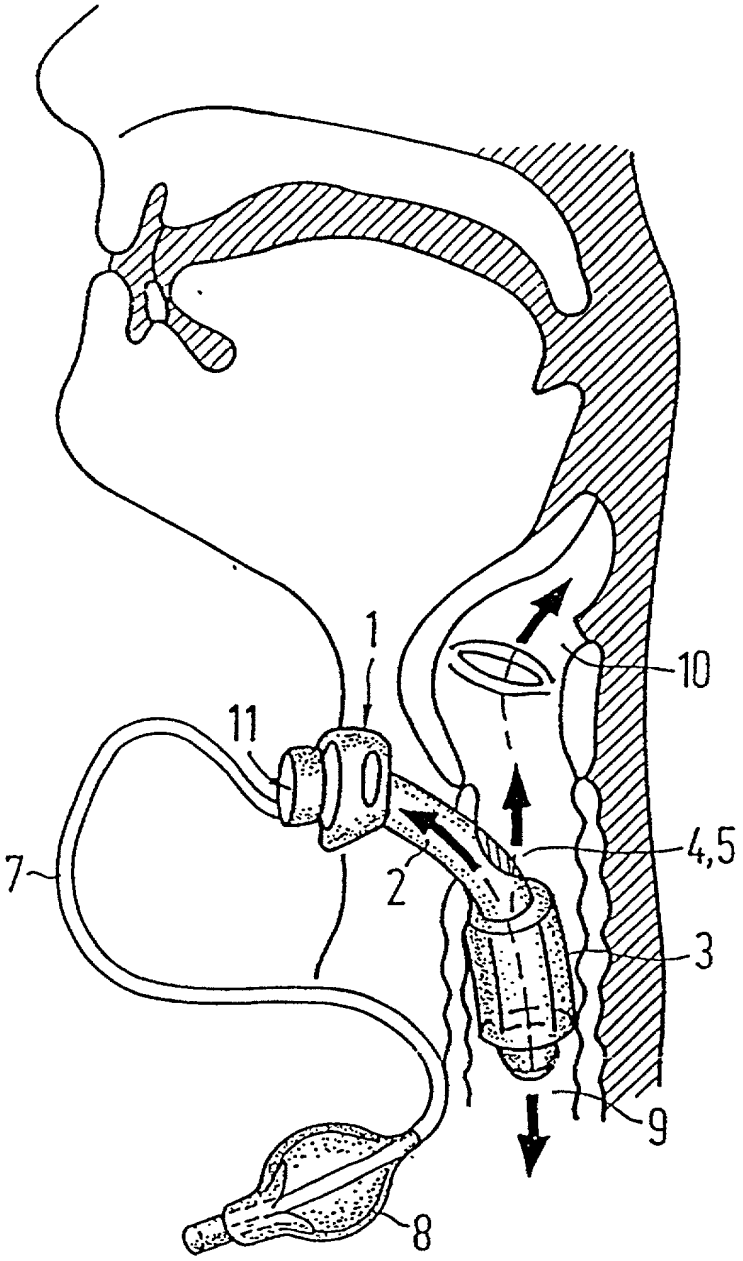

FIG. 2

2/pts

TRACHEAL CANNULA

BACKGROUND OF THE INVENTION

This invention relates to a tracheal cannula for insertion into the trachea following a tracheotomy, with this cannula having a shaft and a cuff for blocking the tracheal cross-sectional area surrounding the shaft.

Following a tracheotomy, a cannula is inserted into the trachea in order to keep open the lumen thereby created. Available to this end are cannulas in diverse forms and made of various materials. Thus, thin-walled silver cannulas are familiar that are constructed in a double-barreled form, namely, they have an outer cannula and an inner cannula that is easy to remove. Furthermore, there are also more thick-walled plastic cannulas that, in contrast to metal cannulas, are not as rigid and that at body temperature conform roughly to the shape of the surrounding space, without their lumen thereby changing.

When there is an increased risk of aspiration, a tracheal cannula with a so-called blocker cuff is used, which is intended to prevent any entering of saliva, gastric juice, or other fluids or food (aspiration). These cuffs are normally positioned around the shaft of the cannula or are integrated within it, and can be inflated in order to conform to the surrounding space of the trachea.

Finally there are artificial larynxes, which are equipped with a valve mechanism and a hole or a screen on their shaft in order to make it possible for the patient to vocalize. When the patient inhales, the valve mechanism at the cannula entrance opens up and permits the intake of air through the cannula into the lungs. On the other hand, in exhalation the valve closes and the air stream is led out through the larynx in a normal way via the cannula hole or window, thus enabling both a normal air intake and also the use of the voice. However, such artificial larynxes can be used only in patients who are not at risk for aspiration, so that those who are at such a risk have no way to speak. Whereas this is still tolerable for patients in the transitional stage immediately after a tracheotomy, the inability to vocalize over a long period of time is quite difficult to accept, especially in the case of neurologically

impaired patients with a protracted risk for aspiration (for example, following a stroke).

Known from US Patent No. 4,459,984 is a tracheal cannula of this species for insertion into the trachea. This device comprises a curved cannula that has an inflatable cuff positioned around the end of the cannula that is within the trachea. Above the cuff, the tracheal cannula has an escape nozzle or opening that can be closed by a flap valve and that can be opened by increasing the air pressure in the tracheal cannula, so that air escapes into the upper esophagus and the patient can speak during the mechanical evacuation of air. However, because of this valve, which is intended to prevent aspiration when in the closed state, the air stream is deflected and slowed down considerably. This causes the natural vocalization characteristics in the larynx to be impaired. Furthermore, when the inner pressure in the tracheal cannula slackens, the valve is abruptly closed and thereby prevents vocalization from continuing. Moreover, due to the possibility that the flap of the valve may jam, a risk of aspiration cannot be excluded with certainty.

Therefore, one object of the invention is to make possible in a reliable way a vocalization that is as natural as possible in patients equipped with tracheal cannulas that have a cuff.

SUMMARY OF THE INVENTION

By means of the invention, this object is essentially achieved by constructing a window in the section of the shaft lying above the cuff, with this window being covered by a membrane that is permeable to air. This membrane thereby prevents the entry of saliva and food particles into the cannula and thus into the lower airways. But on the other hand, speaking is made possible because of the air permeability of the membrane.

In accordance with one preferred embodiment of the invention, the membrane is not permeable to water, so as to ensure that no saliva or nutrient components enter into the cannula. It has turned out to be especially advantageous in this connection to use a membrane made of polytetrafluoroethylene (PTFE), especially a fabric made of PTFE such as can be obtained on the commercial market under the trade name of Gore-Tex®.

In the inhalation process the air is carried through the cannula into the lungs, whereas for speaking purposes the patient can hold closed the cannula in order for the air to go through the membrane into the larynx. However, in accordance with one preferred embodiment of the invention, a provision is made to have a valve situated at the entrance of the cannula, with this valve automatically opening with inhalation and closing with exhalation.

In one improvement of the invention, the cuff is connected via a line to a pilot balloon or the like for the inflation of the cuff and for controlling the cuff pressure.

Other aims, advantages, and possible applications of the invention appear from the following description of an exemplary embodiment and from the drawings. Here all the described and/or graphically represented features form the subject of the invention by themselves or in any given combination, regardless of how they are summarized in the claims or of any of their back-references.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of a tracheal cannula in accordance with the invention, and

Figure 2 is the tracheal cannula shown in schematic fashion when inserted into the trachea of a patient.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

As can be seen from the drawings, a tracheal cannula 1 in accordance with the invention comprises a hollow shaft 2, within whose lower section a cuff 3 is provided. This cuff 3 can be slipped onto the shaft 2 or can be constructed to form a one-piece unit with this. Above the cuff 3 a window 4 is constructed in the shaft 2, with this window being covered with an air-permeable but not water-permeable membrane 5. In one preferred embodiment, the membrane consists essentially of polytetrafluoroethylene (PFTE) or a fabric made of PFTE lacing This membrane preferably is composed of a fabric such as can be obtained on the commercial market under the trade name of Gore-Tex®.

Provided at the front section of the shaft 2 are holding arms 6 by means of which the positioning and attachment of the tracheal cannula 1 on the throat of the patient can be accomplished. Via a line 7, which is connected with a pilot balloon 8, the cuff 3 can be inflated and the cuff pressure can be controlled. The line 7 can be designed to be removable from the cannula.

Following a tracheotomy the tracheal cannula 1 is shown as in Figure 2, with it being inserted into the trachea 9 of the patient. In this connection, it must be made sure that the membrane-protected window 4 of the shaft 2 lies within the tracheal lumen of the trachea 9, so that in an exhalation it is ensured that the air is carried into the larynx 10. After the insertion of the tracheal cannula 1, the cuff 3 is inflated with the aid of the pilot balloon 8 or in some other suitable way such that it conforms to the cross-sectional area of the trachea and thus closes the trachea. Thereby the lungs can be supplied with air only via the cannula 1.

In inhalation, the air is sucked in through the intake 11 of the tracheal cannula 1 and is conveyed into the lungs. When exhaling, a valve, not shown, closes the cannula 1, so that the air stream escapes through the membrane-protected window 4 into the larynx 10 and the patient is rendered able to speak.

In a different, simpler embodiment, no valve is provided in the tracheal cannula 1, so that in order to speak the patient must hold shut the cannula 1 during the exhalation process.

In this way, by means of the invention any entry of fluid into the trachea is reliably prevented, whereas in exhaling the air goes through the membrane into the larynx, so that the patient is able to speak.

What is Claimed:

1. A tracheal cannula for insertion into the trachea following a tracheotomy, having a shaft and a cuff for blocking the tracheal cross-sectional area surrounding the shaft, characterized such that in the section of the shaft lying above the cuff a window is constructed such that this is covered by an air-permeable membrane.

2. Tracheal cannula based on claim 1, characterized such that the membrane is not permeable to water.

3. Tracheal cannula based on claim 2, characterized such that the membrane consists essentially of polytetrafluoroethylene (PTFE).

4. Tracheal cannula based on claim 2, characterized such that the membrane comprises polytetrafluoroethylene (PTFE).

5. Tracheal cannula based on claim 3, characterized such that the membrane comprises a fabric made of PTFE lacing.

6. Tracheal cannula based on claim 4, characterized in that the membrane consists of a fabric made of PTFE lacing.

7. Tracheal cannula based on claim 1, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

8. Tracheal cannula based on claim 2, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

9. Tracheal cannula based on claim 3, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

10. Tracheal cannula based on claim 4, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

11. Tracheal cannula based on claim 5, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

12. Tracheal cannula based on claim 6, characterized such that at the entrance of the cannula, a valve is provided which opens upon inhalation and closes upon exhalation.

13. Tracheal cannula based on claim 1, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

14. Tracheal cannula based on claim 2, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

15. Tracheal cannula based on claim 3, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

16. Tracheal cannula based on claim 4, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

17. Tracheal cannula based on claim 5, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

18. Tracheal cannula based on claim 6, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

19. Tracheal cannula based on claim 7, characterized such that the cuff is connected via a line to balloon means for the inflation of the cuff and for controlling the cuff pressure.

20. Tracheal cannula based on claim 13, wherein said balloon means comprises a pilot balloon.

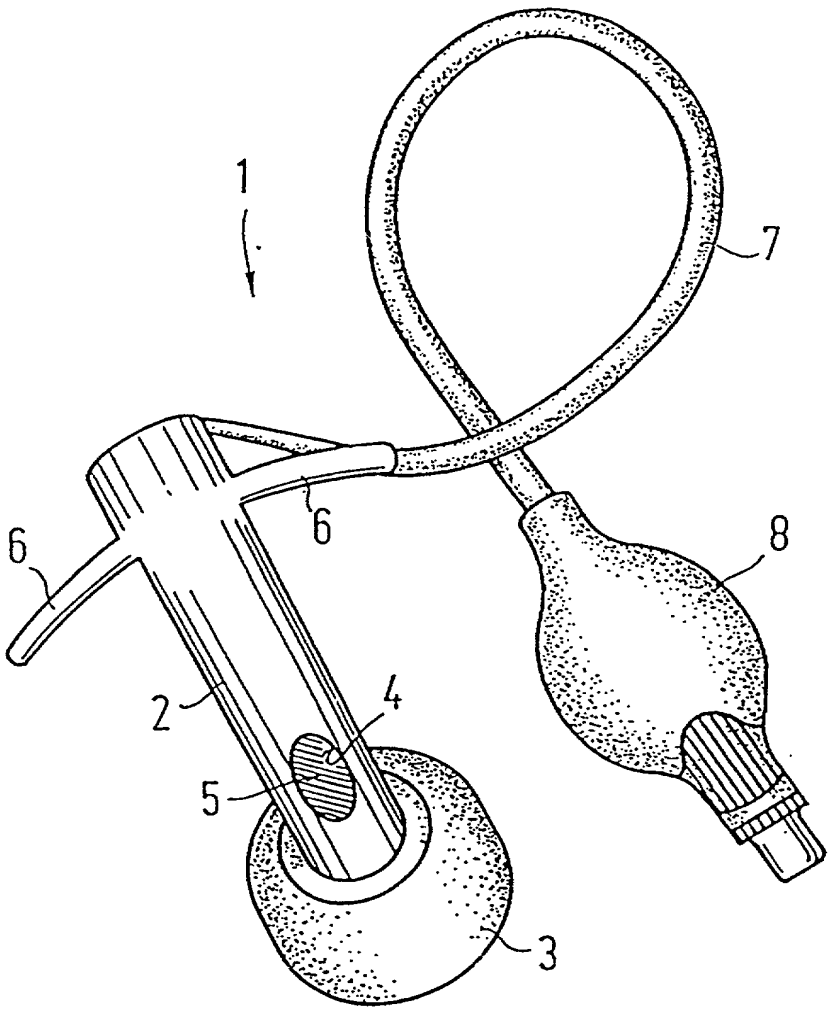

Figure 1

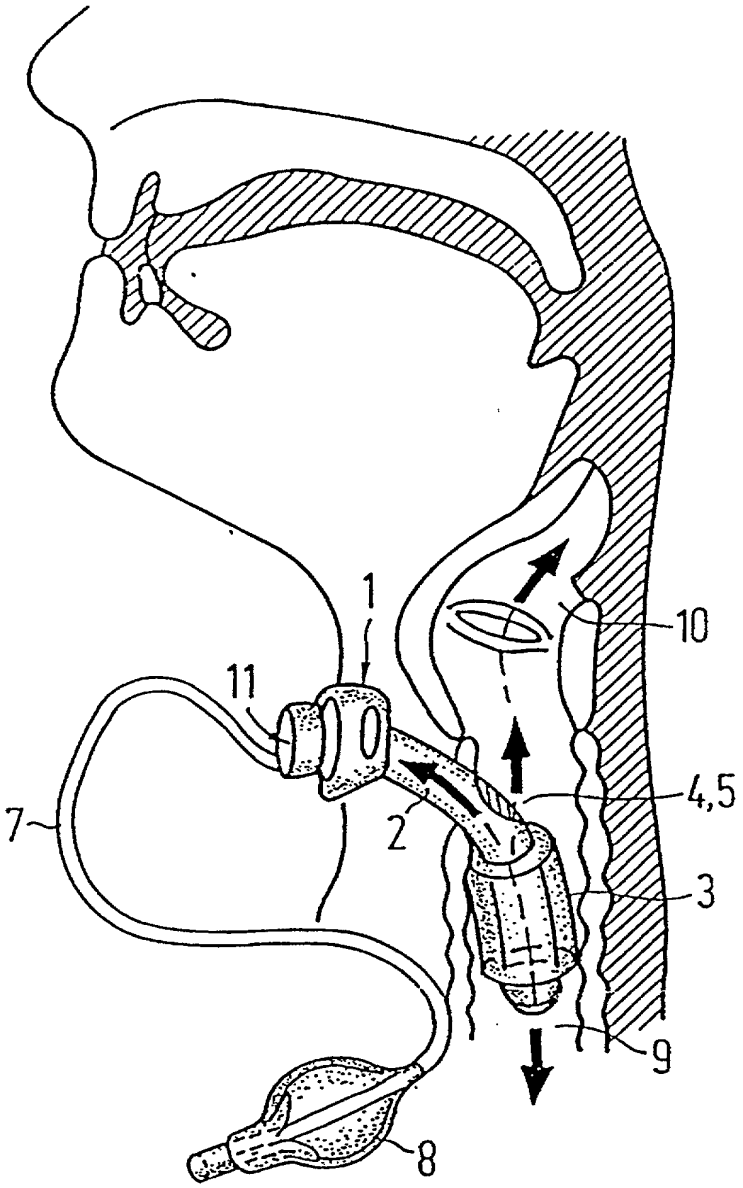

Figure 2

Type a plus sign (+) inside this box → [+]

0010/PTO Rev. 6/95	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket: KEIL/149/PC/US First Named Inventor: Bernhard Eistert

DECLARATION

☒ Declaration Submitted with Initial Filing ☐ Declaration Submitted after Initial Filing

COMPLETE IF KNOWN	
Application Number	
Filing Date	
Group Art Unit	
Examiner Name	

As an above named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Tracheal Cannula

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) August 6, 1999 as United States Application or PCT International Application Number PCT/EP99/05696 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Codes of Federal Regulations, §1.56.

I hereby claim foreign priority under Title 35, United States Code § 119 (a)-(d) or § 365 (b) of any foreign application(s) for patent or inventor's certificate, or § 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Numbers	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Copy Attached Yes	Copy Attached No
PCT/EP99/05696	Germany	August 6, 1999	☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority sheet attached hereto:

I hereby claim the benefit under Title 35, United States Code § 119 (e) of any United States provisional application(s) listed below:

Application Number(s)	Filing Date (MM/DD/YY)	
		☐ Additional provisional application numbers are listed on a supplemental priority sheet attached hereto.

DECLARATION	Page 2

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Title Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

U.S. Parent Application Number	PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT International application numbers are listed on a supplementary priority sheet attached hereto.

As a named inventor, I hereby appoint the registered practitioners associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office therewith, and direct that all correspondence be addressed to that Customer Number:

Firm Name: **Alix, Yale & Ristas, LLP** Customer Number: **002543**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor ☐ A petition has been filed for this unsigned inventor

Given Name	Bernhard	Middle Initial		Family Name	Eistert	Suffix	

Inventor's Signature	B. Eistert	Date	Dec. 1st 2001

RESIDENCE: City	Rothenburg ob der Tauber	State		Country	Germany DEX	Citizenship	Germany

POST OFFICE ADDRESS	Am Katzenbuckel 36

City	Rothenburg ob der Tauber	State		Zip	D-91541	Country	Germany	Applicant Authority	

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name		Middle Initial		Family Name		Suffix	

Inventor's Signature		Date	

RESIDENCE: City		State		Country		Citizenship	

POST OFFICE ADDRESS	

City		State		Zip		Country		Applicant Authority	

☐ Additional inventors are being named on supplemental sheet(s) attached hereto.